

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS**

**LIEUTENANT COLONEL CARLA A.
WIESE,**

Plaintiff,

v.

JOSEPH R. BIDEN, JR., in his official capacity as President of the United States of America, **LLOYD J. AUSTIN, III**, in his official capacity as the United States Secretary of Defense, **FRANK KENDALL**, in his official capacity as the Secretary of the Air Force, and **GENERAL MICHAEL A. MINIHAN**, in his official capacity as Commander of the United States Air Force Air Mobility Command,

Defendants.

Civil Action No. : _____

JURY DEMAND

VERIFIED COMPLAINT

COMES NOW Plaintiff Lieutenant Colonel Carla A. Wiese (hereinafter “Plaintiff”) by and through undersigned counsel, and for her Complaint against **Joseph R. Biden, Jr.**, in his official capacity as President of the United States, **Lloyd J. Austin**, in his official capacity as United States Secretary of Defense, **Frank Kendall**, in his official capacity as Secretary of the Air Force and **General Michael A. Minihan**, in his official capacity as Commander of the United States Air Force Air Mobility Command, and would hereby show unto the Court the following:

I. PARTIES

1. Plaintiff is currently an active-duty Lieutenant Colonel in The United States Air Force.

2. Defendant Joseph R. Biden, Jr. is the President of The United States of America and the Commander in Chief of the Armed Forces. U.S. Const., Art. II, § 2. On or about July 29, 2021, President Biden directed the Department of Defense to unlawfully vaccinate all service members with the COVID-19 vaccine, including Plaintiff.

3. Defendant Lloyd J. Austin, III is the United States Secretary of Defense. Pursuant to President Biden's directive, on August 24, 2021, Secretary Austin issued a memorandum that required the United States Armed Forces to unlawfully vaccinate all service members against COVID-19, which included Plaintiff.

4. Defendant Frank Kendall is the Secretary of the Air Force. On December 7, 2021, Secretary Kendall issued a Memorandum that unlawfully mandated the United States Air Force to vaccinate all of its members, including Plaintiff.

5. Defendant Michael A. Minihan is the commanding general of the Air Mobility Command. On April 12, 2022, General Minihan denied Lt. Col. Wiese's request for a religious accommodation regarding the COVID-19 vaccine.

II. JURISDICTION, VENUE AND STANDING

6. Pursuant to 28 U.S.C. § 1331, this Court has subject matter jurisdiction.

7. Pursuant to 28 U.S.C. § 1346, this Court has jurisdiction because this is a civil action against the United States.

8. Pursuant to 28 U.S.C. § 1361, this Court has jurisdiction to issue a writ of mandamus to compel an officer or employee of the United States to perform a duty owed to Plaintiff.

9. Pursuant to 42 U.S.C. § 2000bb-1(c), this Court has jurisdiction because Plaintiff's exercise of her religious freedom has been burdened by the United States government.

10. Pursuant to 5 U.S.C. §§ 701-06, this Court has jurisdiction to review the Defendants' unlawful actions and enter the appropriate relief under the Administrative Procedure Act.

11. This Court also has jurisdiction to review and enjoin *ultra vires* or unconstitutional agency action through an equitable cause of action. *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689-92 (1949).

12. This Court has authority to award the requested relief pursuant to 42 U.S.C. § 2000bb-1 and *Tanzin v. Tanvir*, 141 S. Ct. 486 (2020); the requested declaratory relief pursuant to 28 U.S.C. §§ 2201–02; the requested injunctive relief pursuant to 5 U.S.C. § 702 and 28 U.S.C. § 2202; and costs and attorneys' fees pursuant to 42 U.S.C. § 1988(b).

13. Venue is proper pursuant to 28 U.S.C. § 1391.

14. Plaintiff has standing for a declaration of her legal rights pursuant to 28 U.S.C. § 2201.

15. Plaintiff has standing for a redress of grievances pursuant to The Constitution of the United States: "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." U.S. Const. amend. I (emphasis added).

16. "This Court's precedents confirm that *the Petition Clause protects the right of individuals to appeal to courts and other forums established by the government for resolution of legal disputes*. '[T]he right of access to courts for redress of wrongs is an aspect of the First Amendment right to petition the government.'" *Borough of Duryea v. Guarnieri*, 564 U.S. 379, 387 (2011) (citing *Sure-Tan, Inc. v. NLRB*, 467 U.S. 883, 896–897, 104 S.Ct. 2803, 81 L.Ed.2d 732 (1984) ; see also *BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 525, 122 S.Ct. 2390, 153 L.Ed.2d 499 (2002) ; *Bill Johnson's Restaurants, Inc. v. NLRB*, 461 U.S. 731, 741, 103 S.Ct. 2161, 76 L.Ed.2d 277

(1983) ; *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972) (emphasis added).

III. STATEMENT OF FACTS

A. **On January 31, 2020, the Secretary of the U.S. Health and Human Services Declared a Public Health Emergency exists.**

17. Pursuant to 21 U.S.C. § 360bbb-3(b)(1), the Health and Human Services Secretary “may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of - ... (C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security... and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents....”

(b) **Declaration of emergency** or threat justifying emergency authorized use

(1) In general

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of-

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with-

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

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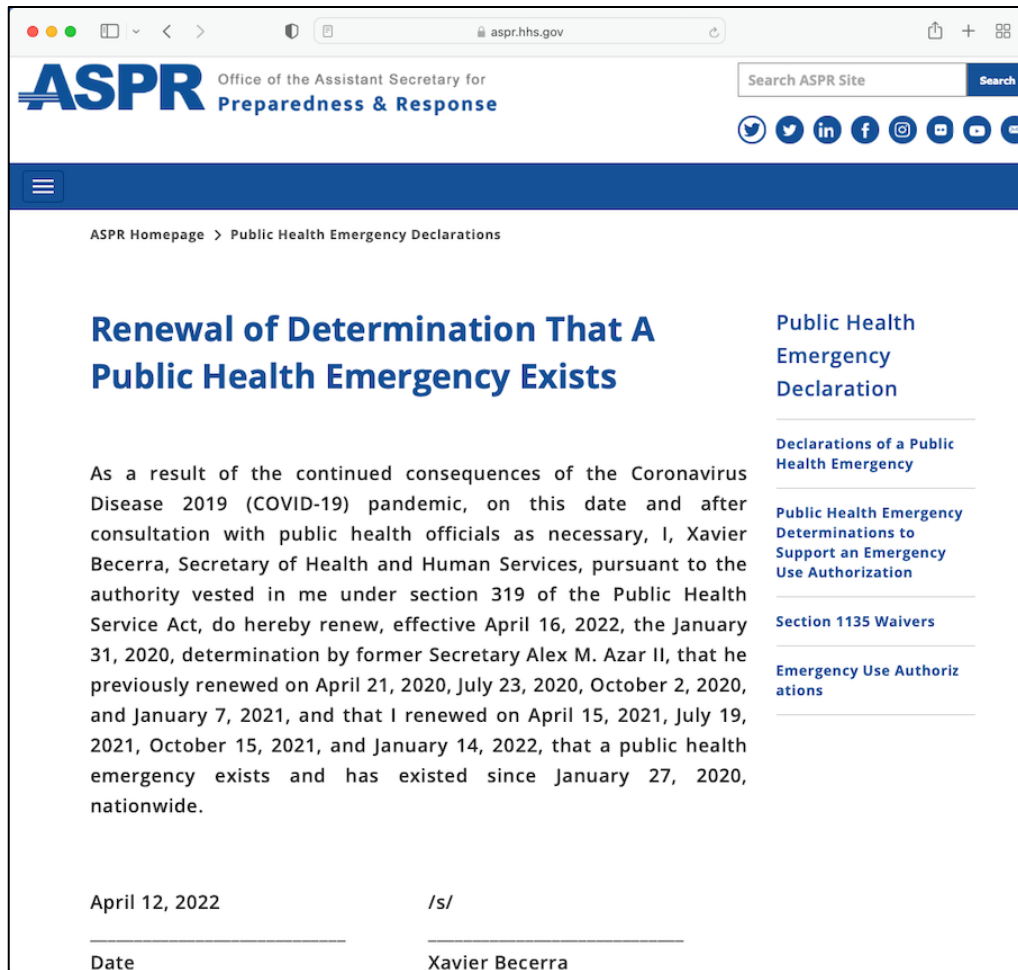
(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

(D) the identification of a material threat pursuant to section 319F-2 of the Public Health Service Act [42 U.S.C. 247d-6b] sufficient to affect national security or the health and security of United States citizens living abroad.

18. On January 31, 2020, The Secretary of Health and Human Services, Alex M. Azar, II, declared a Public Health Emergency. U.S. Department of Health & Human Services, Determination that a Public Health Emergency Exists, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (last visited July 10, 2022).



19. The aforementioned Public Health Emergency was renewed on the following dates: April 2, 2020; April 21, 2020; July 6, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; October 15, 2021; January 14, 2022; and April 12, 2022. Public Health Emergency Declarations, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx> (last visited July 10, 2022).




20. As of the date of this lawsuit, The United States of America has been under a continuous “Determination That A Public Health Emergency Exists” as declared by Secretary of Health and Human Services, Mr. Xavier Bacerra. In other words, the United States has been under a declared Public Health Emergency as a result of COVID-19.

21. On or about July 29, 2021, Defendant Biden directed the Department of Defense to vaccinate all service members, including Plaintiff.

22. On or about August 24, 2021, Defendant Austin issued a Memorandum and Order, which required the United States Armed Forces to mandate the COVID-19 vaccine to all service members, including Plaintiff.

B. Lt. Col. Wiese submitted a “Religious Accommodation Request” to the United States Air Force’s illegal and unlawful COVID-19 vaccine [sic] mandate.

23. On 14 September 2021, Lt. Col. Wiese submitted a “Religious Accommodation Request” for the COVID-19 vaccine [sic] mandate. (attached hereto as Exhibit 1)

	<p style="text-align: center;">DEPARTMENT OF THE AIR FORCE 60TH MEDICAL GROUP (AMC)</p> <p style="text-align: right;">14 September 2021</p> <p>MEMORANDUM FOR AMC/CC</p> <p>FROM: LT COL CARLA A. WIESE/60 MDG</p> <p>SUBJECT: Religious Accommodation Request – Vaccine Exemption</p> <p>1. I request an accommodation waiver of the COVID-19 vaccine requirement based upon my religious, conscience, and moral beliefs being a Roman Catholic.</p> <p>a. My DoD ID number is [REDACTED]</p> <p>b. My Specialty Code is [REDACTED]</p> <p>c. My unit of assignment is 60th MDG.</p> <p>d. My faith group of preference is Roman Catholic.</p>
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24. In her Religious Accommodation Request, Lt. Col. Wiese expressly stated her religious, conscience and moral objections to receiving the COVID-19 vaccine [sic]. Lt. Col. Wiese expressly stated that she objects to receiving this injection on the basis that:

1) **abortion is a sin** and **aborted fetal cells are used in the making of the COVID-19 vaccines**, and 2) **my Catholic belief that I am made in God’s image and nothing is to alter that**. The vaccines are made with mRNA technology for gene therapy and alter one’s genetic makeup, if received. **The receipt of this shot would violate my religious beliefs, as stated above, and I would not be able to practice my faith as a Roman Catholic. My conscience and moral beliefs would be directly violated if I receive this shot.** For consideration, I provide the following bible reference: Genesis 1:26-27, Then God said, “Let us make man in our image, after our likeness. And let them have dominion over the fish of the sea and over the birds of the heavens and over the livestock and over all the earth.” So God created man in his own image, in the image of God

he created him; male and female he created them. I understand I must arrange an in-person interview with a Department of the Air Force chaplain and an in-person appointment with an appointed Air Force medical provider as part of the process for requesting a religious accommodation.

1. I request an accommodation waiver of the COVID-19 vaccine requirement based upon my religious, conscience, and moral beliefs being a Roman Catholic.

- a. My DoD ID number is [REDACTED]
- b. My Specialty Code is [REDACTED]
- c. My unit of assignment is 60th MDG.
- d. My faith group of preference is Roman Catholic.

2. This request is based on the basis that 1) abortion is a sin and aborted fetal cells are used in the making of the COVID-19 vaccines, and 2) my Catholic belief that I am made in God's image and nothing is to alter that. The vaccines are made with mRNA technology for gene therapy and alter one's genetic makeup, if received. The receipt of this shot would violate my religious beliefs, as stated above, and I would not be able to practice my faith as a Roman Catholic. My conscience and moral beliefs would be directly violated if I receive this shot. For consideration, I provide the following bible reference: Genesis 1:26-27, Then God said, "Let us make man in our image, after our likeness. And let them have dominion over the fish of the sea and over the birds of the heavens and over the livestock and over all the earth." So God created man in his own image, in the image of God he created him; male and female he created them. I understand I must arrange an in-person interview with a Department of the Air Force chaplain and an in-person appointment with an appointed Air Force medical provider as part of the process for requesting a religious accommodation.

25. After Lt. Col. Wiese submitted her Religious Accommodation Request – Vaccine [sic] Exemption, the United States Air Force retaliated by forcing Lt. Col. Wiese to undergo multiple counseling sessions and to meet with a chaplain and medical provider to counsel her on the potential consequences of refusing to comply with the USAF's unlawful order.

26. The consequences included, but were not limited to, being found: (1) unfit for deployment; (2) unfit for assignment; (3) disqualified for international travel; (4) unfit for continued service; and (5) other potential administrative consequences not yet disclosed.

27. Despite the United States Air Force's retaliation, Lt. Col. Wiese continued to assert her constitutional right to bodily autonomy and to refuse unwanted medical treatment in the form of an unapproved and experimental vaccine [sic].

28. On or about 18 October 2021, Lt. Col. Wiese attended required counseling for her religious accommodation request to the COVID-19 vaccine [sic] mandate.

29. The United States Air Force conducted an inquisition of Lt. Col. Wiese's sincerely held religious beliefs.

30. Colonel Steven Richardson interviewed Lt. Col. Wiese on 18 October 2021.

31. Colonel Richardson tested Lt. Col. Wiese's sincerely-held religious beliefs by offering possible scenarios and consequences of approval or denial of the accommodation.

32. Lt. Col. Wiese's religious belief is that the COVID-19 vaccine [sic] was developed using fetal cell lines taken from elective abortions and receiving the shot would violate her conscience and clear understanding of Christian biblical scriptures.

33. Based upon her medical background, Lt. Col. Wiese also believes that the COVID-19 vaccine [sic] alters a person's DNA.

34. As such, it would violate Lt. Col. Wiese's understanding of her body as purposefully made by God and that taking said vaccine [sic] would cause great harm to her mental health and spiritual health.

35. After his interview, Col. Richardson concluded that "I believe Lt Col Wiese is sincere in her religious belief and being forced to take the COVID vaccine [sic] would cause great harm to her mental health and spiritual health. Lt Col Wiese is willing to take any other precaution necessary to prevent the spread of COVID including wearing a mask and socially distancing. There are no inconsistencies between her practice and beliefs." (Religious Accommodation Interview attached hereto as Exhibit 2).

C. **The United States Air Force denied Lt. Col. Wiese's Religious Accommodation Request to the COVID-19 vaccine [sic] mandate.**

36. On April 12, 2022, General Michael A. Minihan issued a "MEMORANDUM FOR LIEUTENANT COLONEL CARLA WIESE" that contained his decision to deny Lt. Col. Wiese's request for a religious accommodation. (Denial of Lt. Col. Wiese's Religious Accommodation Request is attached hereto as Exhibit 3).

37. Specifically, General Minihan denied her Religious Accommodation Request because General Minihan "disapproved" of Lt. Col. Wiese's sincerely held religious beliefs as a Roman Catholic Christian.

38. General Minihan stated that "I have received your request for a religious accommodation to be exempt from the COVID-19 vaccine [sic]." *Id.*

39. "After careful consideration of the specific facts and circumstances, **I disapprove your request for accommodation. Regardless of whether you have a sincerely held religious belief**, the Air Force has a compelling government interests in ensuring mission accomplishment, of which health and safety are necessary elements, and the prevention of COVID-19." *Id.* (emphasis added).



**DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR MOBILITY COMMAND**

APR 12 2022

MEMORANDUM FOR LIEUTENANT COLONEL CARLA WIESE, 60 MDG

FROM: AMC/CC

SUBJECT: Decision Regarding Religious Accommodation Request – Lt Col Carla Wiese

1. I have received your request for religious accommodation to be exempt from the COVID-19 vaccine.

2. After careful consideration of the specific facts and circumstances, I disapprove your request for accommodation. Regardless of whether you have a sincerely held religious belief, the Air Force has compelling government interests in ensuring mission accomplishment, of which health and safety are necessary elements, and the prevention of COVID-19.

40. The reasons for denying Lt. Col. Wiese's sincerely held religious beliefs were predicated upon "ensuring mission accomplishment, of which health and safety are necessary elements, and the prevention of COVID-19." *Id.*

41. However, General Minihan fails and/or refuses to understand that the COVID-19 vaccine [sic] does not provide greater protection than natural immunity.

D. Medical doctors have testified that there is no evidence that the COVID-19 vaccines provide superior immunity than natural immunity.

42. Dr. Peter McCullough is a subject matter expert on the COVID-19 vaccines [sic]. Dr. McCullough provided sworn testimony to the United States District Court, Middle District of Tennessee, Nashville Division that "To my knowledge, **there are no studies that demonstrate the clinical benefit of COVID-19 vaccination** in COVID-19 survivors or those with suspected COVID-19 illness of subclinical disease who have laboratory evidence of prior infection." *Avery Garfield v. Middle Tennessee State University and Dr. Jenny Sauls*, Case No. 3:21-cv-00613, Plaintiff Avery Garfield's Rule 26 Disclosures, p. 36 of 225, ¶ 74 (attached hereto as Exhibit 4) (emphasis added).

43. Dr. Peter McCullough further opined that:

75. It is my opinion that SARS-CoV-2 causes an infection in humans that **results in robust, complete, and durable immunity, and is superior to vaccine immunity**, which by comparison has demonstrated massive failure including over 10,000 well-documented vaccine failure cases as reported by the CDC **before tracking was stopped** on May 31, 2021. **There are no studies demonstrating the clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals.** Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors, many of whom may be in the student population.

76. Multiple laboratory studies conducted by highly respected U.S. and European academic research groups have reported that convalescent **mildly or severely infected COVID-19 patients who are unvaccinated can have greater virus-neutralizing immunity**—especially more versatile, long-enduring T- cell immunity—relative **to vaccinated individuals who were never infected**. See Athina Kilpeläinen, et al., Highly functional Cellular Immunity in SARS-CoV-2 Non-Seroconvertors is associated with immune protection, bioRxiv (pre-print), <https://www.biorxiv.org/content/10.1101/2021.05.04.438781v1> (last visited June 26, 2021); Tongcui Ma, et al., Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence, bioRxiv (pre-print), <https://www.biorxiv.org/content/10.1101/2021.04.28.441880v1> (last visited June 26, 2021); Claudia Gonzalez, et al., Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2, medRxiv (pre-print), <https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1> (last visited June 21, 2021); Carmen Camara, et al. Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals, bioRxiv (pre-print), <https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1> (last visited June 26, 2021); Ellie N. Ivanova, et al., Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection, medRxiv (pre-print), <https://www.medrxiv.org/content/10.1101/2021.04.20.21255677v1> (last visited June 26, 2021); Catherine J. Reynolds, et al., Prior SARS-CoV-2 infection rescues B and T cell responses to variants after first vaccine dose, (pre-print), <https://pubmed.ncbi.nlm.nih.gov/33931567/> (last visited June 21, 2021); Yair Goldberg, et al., Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel, medRxiv (pre-print), <https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1> (last visited June 26, 2021).

Id at ¶¶ 75-76 (emphasis added).

44. Dr. Peter McCullough concluded his expert report with the following medical opinions as a subject matter expert on the COVID-19 vaccines [sic]:

CONCLUSION

In my expert medical opinion, despite the current Delta variant outbreak, increasing likelihood of herd immunity to COVID-19, the low risk to children and young adults of serious complications or death due to COVID-19, the negligible risk of asymptomatic spread of COVID-19, the vastly improved COVID-19 treatments currently available all make the risks inherent in COVID-19 significantly lower than they were in 2020.

It is my expert medical opinion that the Pfizer vaccine as tested in young adults does not offer a significant clinical benefit and has a poor benefit to risk ratio as tested in randomized

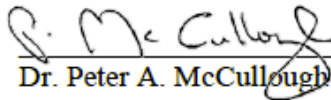
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trials in the era of the now extinct SARS-CoV-2 wild-type, alpha, beta, and gamma variants.. Vaccination to prevent mild viral upper respiratory symptoms in a small fraction (1.6%) of subjects is not justified given the short and longer-term risks of the vaccines.

It is my expert medical opinion that the COVID-19 vaccines are progressively losing efficacy over the prevention of COVID-19 and in widely vaccinated countries up to 80% of COVID-19 cases have been in the previously vaccinated, implying the vaccines have become obsolete with antigenic escape or resistance to variants (e.g. Delta) that have evolved to infect persons who were vaccinated against the now extinct wild-type SARS-CoV-2 strain. Thus, COVID-19 vaccination does not make a person less infectious nor does it “protect” others.

It is my expert medical opinion that it is dangerous research or clinical practice to widely utilize novel biologic therapy (mRNA, adenoviral DNA COVID-19 vaccines) in populations where there is no information generated from the registrational trials with the FDA, specifically, children and adolescents, COVID-19 survivors, suspected COVID-19-recovered, pregnant or women who could become pregnant at any time after investigational vaccines. In my expert medical opinion, the risks associated with the investigational COVID-19 vaccines, especially those more prevalent among children and adolescents, far outweigh any theoretical benefits, are not minor or unserious, and many of those risks are unknown or have not been adequately quantified nor has the duration of their consequences been evaluated or is calculable. Therefore, in my expert medical opinion, the administration of COVID-19 vaccines for children and adolescents aged 12-15 creates an unethical, unreasonable, clinically unjustified, unsafe, and poses an unnecessary risk to the children of the United States of America.

 19-OCT-2021
Dr. Peter A. McCullough

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45. Dr. Craig Wax had similar conclusions as a subject matter expert on the COVID-19 vaccines [sic]:

As to my expert opinion:

Methodologies and Analysis of COVID-19 Vaccines

8. Every medical procedure, surgery, medication and vaccination must be preceded by standard informed consent (consistent with the Declaration of Helsinki), where

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Craig M. Wax, D.O., L.L.C. – Family Medicine and Health

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proposed benefits, risks and alternatives are disclosed and accepted by the patient with their own freewill. This must be unencumbered by coercion, pressure, threats, or inducements (consistent with the Nuremburg Code). The COVID-19 vaccine process violates the medical standard of informed consent.

9. Every medical procedure, surgery, medication and vaccination must have standard right of refusal. All individual patients must have the right to refuse medical procedures, etc. The COVID-19 vaccine process violates the standard right to refuse.
10. Current clinical medical practice features Shared Decision Making, where patient and physician share in the process. The COVID-19 vaccine process violates Shared Decision Making by mandates.

11. Current state and federal vaccine laws allow for both broad religious and medical exemptions on a case-by-case basis. The COVID-19 vaccine process violates standard exemptions by making patient sincerely held beliefs and physician clinical judgement ineligible for exemption.
12. The scientific method of study generally includes a double blinded cohort with a control group that does not receive the substance under testing. The COVID-19 vaccine protocol has violated the standard scientific method as there is no control group with “all-in” mandates by government force majeure.
13. Every human being has the right to body autonomy and self-determination. The COVID-19 vaccine process has violated each individual’s body autonomy and self-determination rights.

Craig M. Wax, D.O., L.L.C. – Family Medicine and Health

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14. The COVID-19 vaccines feature an unproven technology that has never been FDA approved for safety in human use before. With more reported adverse events in their first year of (forced) mass-execution than all other vaccines in VAERS database combined, The COVID-19 vaccine process violates the standards of safety.

15. As of October 19, 2021, no COVID-19 vaccine has completed the clinical trials and has been approved by the FDA.
16. As of October 19, 2021, the Janssen COVID-19 vaccine has not completed its clinical trials and said vaccine has not been approved by the FDA.
17. As of October 19, 2021, the Moderna COVID-19 vaccine has not completed its clinical trials and said vaccine has not been approved by the FDA.
18. As of October 19, 2021, the Pfizer BioNTech COVID-19 vaccine has not completed its clinical trials and said vaccine has not been approved by the FDA.
19. As of October 19, 2021, the COMIRNATY (COVID-19 Vaccine, mRNA) has not completed its clinical trials and said vaccine has not been approved by the FDA.
20. As of October 19, 2021, all COVID-19 vaccines that are currently being administered in the United States are administered pursuant to the Emergency Use Authorization.
21. As of October 19, 2021, no COVID-19 vaccines are proven to prevent SARS-CoV-2 (COVID-19) virus or person-to-person transmission or spread.

/s/ Craig M. Wax

Dr. Craig M. Wax
Family Physician

Id at pp. 215-17.

E. During a Public Health Emergency, federal law permits use of unapproved medical products, but said unapproved medical products cannot be mandated.

46. During a Public Health Emergency, the Health and Human Services Secretary “may authorize ... during the effective period of a declaration [of a state of emergency] ... a drug, device, or biological product intended for use in an actual or potential emergency.... [The Secretary] may authorize an emergency use of a product that – (A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. § 262] or conditionally approved under section 360ccc of this title ... (referred to in this section as unapproved product)....” 21 U.S.C. § 360bbb-3(a)(1)-(2).

§360bbb–3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that-

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an “unapproved product”); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an “unapproved use of an approved product”).

F. There is no FDA-approved COVID-19 vaccine [sic]. All COVID-19 vaccines [sic] are administered under the Emergency Use Authorization.

1. The Johnson & Johnson Janssen COVID-19 injection is not approved by the FDA.

47. As of July 10, 2022, there are no FDA-approved COVID-19 vaccines [sic].

48. The Janssen COVID-19 injection itself has not been approved by the FDA. Fact

Sheet for Healthcare Providers Administering Vaccine [sic],

<https://www.fda.gov/media/146304/download> (Last visited on July 10, 2022) (attached hereto as Exhibit 5). The fact sheet was last revised/updated on January 31, 2022. *Id.*

**FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)**

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the **unapproved product, the Janssen COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, **you must communicate to the recipient** or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the

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individual to the website www.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- **FDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an FDA approved vaccine.**
- **The recipient** or their caregiver **has the option to** accept or **refuse** the Janssen COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

49. As of August 2, 2021, the Janssen COVID-19, “The Janssen COVID-19 Vaccine is an **unapproved vaccine**....” *Id* (emphasis added).

50. As you can see from the Janssen Fact Sheet, healthcare providers (which includes the United States Air Force) are required by federal law, discussed at length *infra*, to communicate certain information to the recipient of the unapproved injection. *See id*.

51. Since the United States Air Force is administering COVID-19 injections, the United States Air Force is required by federal law to notify the recipient that the injection has not been approved by the FDA.

52. In their own words, Johnson and Johnson admits that its COVID-19 injection has not been approved by the FDA and that it is being administered pursuant to the Emergency Use Authorization: “FDA has authorized the **emergency use** of the Janssen COVID-19 Vaccine, **which is not an FDA approved vaccine**.” *Id* (emphasis added).

53. Moreover, as required by federal law, discussed *infra*, the recipient must be provided the option to refuse this injection. *Id*.

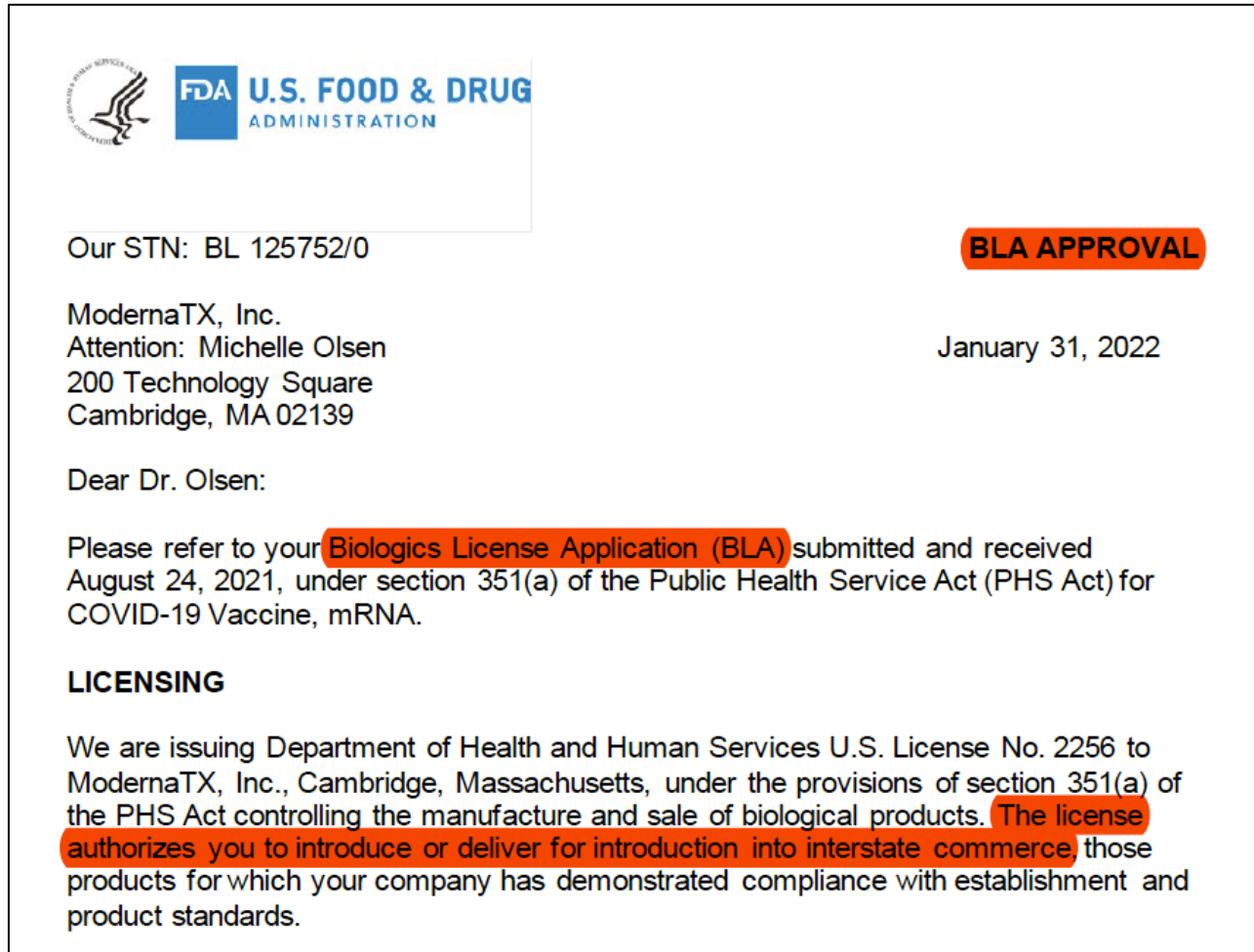
54. The Air Force must notify Lt. Col. Wiese of her right and option to refuse this unapproved and experimental COVID-19 injection.

2. **The Moderna and Spikevax COVID-19 vaccines are not approved by the FDA. These injections have had a Biologics License Application (BLA) approved by the FDA, which only permits Moderna to begin a clinical trial of the experimental injections.**

55. “On December 18, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Moderna COVID-19 Vaccine [sic]” Emergency Use Authorization (EUA) for an Unapproved Product, <https://www.fda.gov/media/144673/download> (last visited July 10, 2022) (attached hereto as Exhibit 6).

56. The FDA's Letter of Authorization was reissued on: February 25, 2021, July 7, 2021, August 11, 2021, October 20, 2021, November 19, 2021, and January 7, 2022.

57. "On January 31, 2022, the FDA approved [a Biologics License Application and not the injection itself] SPIKEVAX (COVID-19 Vaccine [sic] and certain uses of SPIKEVAX (COVID-19 Vaccine [sic], mRNA)." (Letter attached hereto as Exhibit 7).



58. The SPIKEVAX (COVID-19 Vaccine [sic], mRNA) had its Biologics License Application (*i.e.*, permission to start a clinical trial of an experimental injection) approved by the FDA on January 31, 2022. The FDA's BLA Approval Letter dated January 31, 2022, <https://www.fda.gov/media/155815/download> (last visited on July 10, 2022).

59. Moreover, the Package Insert for SPIKEVAX clearly discusses “study participants” during “clinical trials” that are subjected to the “Emergency Use Authorization” restrictions. *See* Package Insert for SPIKEVAX (COVID-19 Vaccine [sic], mRNA), <https://www.fda.gov/media/155675/download> (last visited July 10, 2022).

6 ADVERSE REACTIONS

In study participants 18 through 64 years of age, the most commonly reported ($\geq 10\%$) adverse reactions following any dose were pain at injection site (93.3%), fatigue (71.9%), headache (68.7%), myalgia (64.8%), chills (49.7%), arthralgia (48.6%), nausea/vomiting (25.7%), axillary swelling/tenderness (22.2%), fever (17.3%), swelling at the injection site (15.4%), and erythema at the injection site (10.5%).

In study participants 65 years of age and older, the most commonly reported ($\geq 10\%$) adverse reactions following any dose were pain at injection site (88.3%), fatigue (64.8%), headache (53.3%), myalgia (51.8%), arthralgia (40.2%), chills (32.7%), nausea/vomiting (15.0%), swelling at the injection site (13.0%), and axillary swelling/tenderness (12.7%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of SPIKEVAX was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,346 participants 18 years of age and older who received at least one dose of SPIKEVAX ($n=15,184$) or placebo ($n=15,162$) (Study 1, NCT04470427). Upon issuance of the Emergency Use Authorization (December 18, 2020) for Moderna COVID-19 Vaccine (SPIKEVAX), participants were unblinded in a phased manner over a period of months to offer placebo participants SPIKEVAX. The median duration of follow up for safety after the second injection during the blinded phase was 4 months. The median duration of follow up for safety after the second injection including both the blinded phase and the open-label phase was 6 months.

60. Similar to the SPIKEVAX, the Moderna COVID-19 Vaccine [sic] is authorized to be administered pursuant to the Emergency Use Authorization. Moderna COVID-19 Vaccine [sic] Letter of Authorization dated June 17, 2022, <https://www.fda.gov/media/144636/download> (last visited July 10, 2022) (attached hereto as Exhibit 8).

61. Moderna's COVID-19 Vaccine [sic] Letter of Authorization was reissued on March 29, 2022. *Id.* The Letter of Authorization for the Moderna COVID-19 Vaccine [sic] clearly states that it is being administered under the Emergency Use Authorization. *Id.*

The Moderna COVID-19 Vaccine (supplied in multiple-dose vials with red caps and labels with light blue borders) and Spikevax (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness. Accordingly, under this EUA, the Moderna COVID-19 Vaccine (supplied in multiple-dose vials with red caps and labels with light blue borders) and Spikevax (COVID-19 Vaccine, mRNA) can be used interchangeably to provide the primary series doses and booster doses without presenting any safety or effectiveness concerns.

Additionally, the SPIKEVAX (COVID-19 Vaccine, mRNA) and the two EUA-authorized presentations of the Moderna COVID-19 Vaccine (one that is supplied in multiple-dose vials with red caps and labels with light blue borders, and the other that is supplied in multiple-dose vials with dark blue caps and labels with purple borders) can be used to provide the first and/or second booster dose in eligible populations. As described below under Product Description, SPIKEVAX (COVID-19 Vaccine, mRNA) and the two presentations of the Moderna COVID-19 Vaccine contain the same ingredients. The concentrations of some of the ingredients differ between the two presentations. Each booster dose of the vaccine (whether Spikevax, the Moderna COVID-19 vaccine supplied in multidose vials with red caps and labels with light blue borders or supplied in multidose vials with dark blue caps and labels with purple borders) contains 50 µg of mRNA encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2.

3. **The Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA) and COMIRNATY (COVID-19 Vaccine [sic], mRNA) injections are not FDA-approved. Both of the Pfizer injections have had their Biologics License Application (BLA) approved by the FDA, which only permits them to begin a clinical trial of the experimental injection.**

62. Neither the Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA) nor the COMIRNATY (COVID-19 Vaccine [sic], mRNA) have been approved by the FDA.

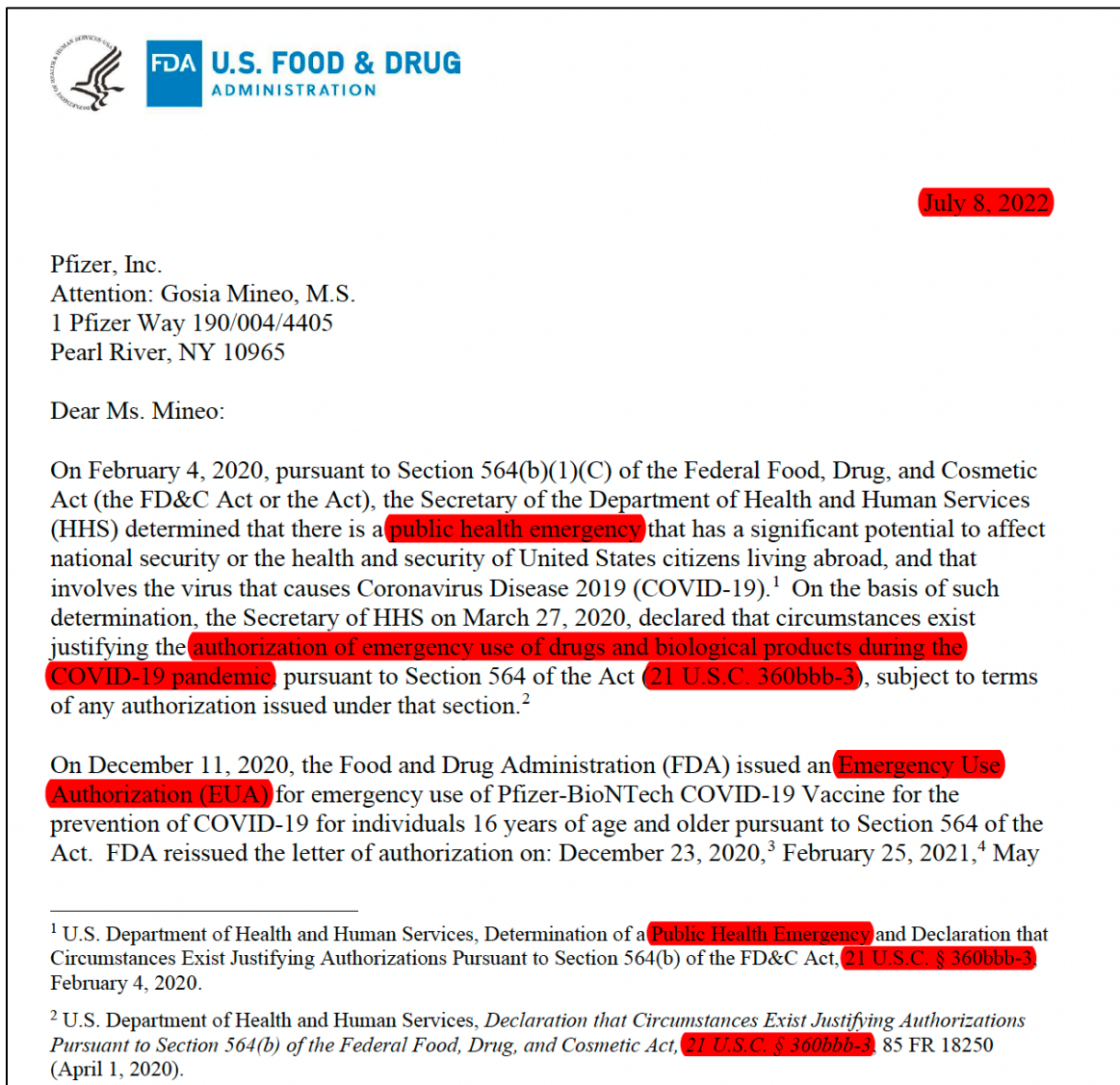
63. Instead, the FDA has approved the Biologics License Application (BLA) for both Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA) and COMIRNATY (COVID-19 Vaccine [sic], mRNA).

64. On December 11, 2020, the FDA issued an Emergency Use Authorization for emergency use of Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA). Emergency Use Authorization for an Unapproved Product Review Memorandum,

<https://www.fda.gov/media/144416/download> (last visited July 10, 2022) (attached hereto as Exhibit 9).

65. The Emergency Use Authorization has been reissued; the most recent Emergency Use Authorization was issued on July 8, 2022. Letter of Authorization, <https://www.fda.gov/media/150386/download> (last visited July 10, 2022) (copy attached hereto as Exhibit 10).

66. The July 8, 2022, Letter of Authorization expressly states “that circumstances exist justifying the **authorization of emergency use** of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. § 360bbb-3), **subject to terms of any authorization issued under that section.**” *Id.*



67. The July 8, 2022, Letter of Authorization authorized Pfizer to manufacture and supply the Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA). *Id* (emphasis added).

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),²² to emergency response stakeholders²³ as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider²⁴ without an individual prescription for each vaccine recipient.
- The Pfizer-BioNTech COVID-19 Vaccine formulations that use either Tris or PBS buffer, as described in more detail under *Product Description* and covered by this authorization, will be administered by vaccination providers to provide for the uses described in Table 1.

68. The July 8, 2022 Letter of Authorization for Pfizer-BioNTech (COVID-19 Vaccine [sic], mRNA) also “covers the use of the licensed COMIRNATY (COVID-19 Vaccine [sic], mRNA) product....” *Id*.

- The vaccine will be administered by vaccination providers and used only to prevent COVID-19 with a two-dose primary regimen (3 weeks apart).

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: (1) a two-dose primary regimen (0.3 mL each, 3 weeks apart) for individuals 12 through 15 years of age; (2) a third primary series dose at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an

69. On August 23, 2021, the United States Food & Drug Administration issued a letter purporting to “approve” the Pfizer injection (but it did not).

70. Instead of approving the injection, the Biologics License Application (BLA) was approved by the FDA to start a clinical trial. FDA Letter dated August 23, 2021, <https://www.fda.gov/media/151710/download> (last visited July 10, 2022) (attached as Exhibit 11).



**FDA U.S. FOOD & DRUG
ADMINISTRATION**

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to **Section 564(b)(1)(C)** of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a **public health emergency** that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).¹ **On the basis of such determination,** the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the **authorization of emergency use of drugs and biological products during the COVID-19 pandemic,** pursuant to **Section 564 of the Act (21 U.S.C. 360bbb-3),** subject to terms of any authorization issued under that section.²

On December 11, 2020, the Food and Drug Administration (FDA) issued an **Emergency Use Authorization (EUA)** for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA **reissued the letter of authorization** on: December 23, 2020,³ February 25, 2021,⁴ May

¹ U.S. Department of Health and Human Services, Determination of a **Public Health Emergency** and Declaration that Circumstances Exist Justifying **Authorizations Pursuant to Section 564(b)** of the Federal Food, Drug, and Cosmetic Act, **21 U.S.C. § 360bbb-3** February 4, 2020.

² U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, **21 U.S.C. § 360bbb-3** 85 FR 18250 (April 1, 2020).

71. “On August 23, 2021, the **FDA approved** the **biologics license application (BLA)** submitted by BioNTech Manufacturing GmbH **for COMIRNATY (COVID-19 Vaccine, mRNA)** for active immunization and to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.” FDA August 23, 2021 Letter to Pfizer (emphasis added) (attached as Exhibit 12).

On August 23, 2021, **FDA approved the biologics license application (BLA)** submitted by BioNTech Manufacturing GmbH **for COMIRNATY (COVID-19 Vaccine, mRNA)** for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

72. On the FDA’s August 23, 2021 letter, the FDA stated that it did the following: “the FDA is **reissuing** the August 12, 2021 **letter of authorization in its entirety** with revisions incorporated to clarify that the **EUA will remain in place** for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses....”

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

73. The Pfizer-BioNTech COVID-19 vaccine was not “approved” by the FDA’s letter.

74. The Pfizer-BioNTech COVID-19 vaccine is not approved by the FDA.

75. The Pfizer-BioNTech COVID-19 vaccine is only authorized for use under the Emergency Use Authorization pursuant to 21 U.S.C. § 360bbb-3.

76. Additionally, the FDA decided “to **authorize use** of **COMIRNATY (COVID-19 Vaccine mRNA) under this EUA for certain uses** that are not included in the **approved BLA**.” *Id.*

77. The FDA’s August 23, 2021, letter was used only to “**authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA**.”

78. The COMIRNATY (COVID-19 Vaccine, mRNA) was not “approved” in this August 23, 2021 FDA letter.

79. The COMIRNATY (COVID-19 Vaccine, mRNA) is not “approved” by the FDA.

80. The two vaccines that are the subject of the FDA's August 23, 2021 letter were not approved by the FDA in this letter.

81. The letter "approved" the BLA for COMIRNATY. COMIRNATY was slid under the umbrella of this Emergency Use Authorization as well to be used for purposes that are not included in their approved biologics license application.

82. The August 23, 2021, FDA letter only "approved" the BLA application, which was submitted by BioNTech Manufacturing GmbH for COMIRNATY.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

83. However, in its letter, the FDA curiously admitted that COMIRNATY (COVID-19 Vaccine, mRNA) has the exact same formulation as the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.⁸

84. COMIRNATY(COVID-19 Vaccine, mRNA) has "the same formulation" as the Pfizer-BioNTech COVID-19 Vaccine.

85. Pfizer-BioNTech COVID-19 Vaccine has "the same formulation" as COMIRNATY(COVID-19 Vaccine, mRNA).

86. Driving the point home further, in Footnote 8, the FDA admitted that it authorized the use of two “legally distinct” vaccines in an FDA “approval” letter (which “approved” a BLA and not a vaccine [sic]) even though they have “the same formulation” and “the products can be used interchangeable to provide the vaccination series....” FDA’s August 23, 2021 Letter, Footnote 8.

⁸ The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

87. In other words, the two COVID-19 vaccines have different names and the “products are legal distinct” but they are really the same because they have “the same formulation” as the other and “the products can be used interchangeably.” *See id.* Different name; same formulation. *Id.*

88. Since the two Pfizer COVID-19 vaccines are not FDA approved and all COVID-19 vaccines are authorized under the Emergency Use Authorization pursuant to 21 U.S.C. § 360bbb-3, the analysis after the FDA’s August 23, 2021 “approval” letter remains the same as before.

89. The vaccines were authorized under an EUA “pursuant to Section 564 of the Act (21 U.S.C. § 360bbb-3), **SUBJECT TO TERMS** of any authorization issued **under that section**.” *Id.*

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).¹ On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.²

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,³ February 25, 2021,⁴ May

¹ U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

² U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

90. None of the COVID-19 vaccines [sic] have been approved by the FDA.

91. The FDA has approved the Biologics License Application (BLA), which permits each company to begin a clinical trial of their medical product.

92. All of the COVID-19 injections are administered under an Emergency Use Authorization, which has very strict requirements prior to being administered.

G. During a declared Public Health Emergency, federal law permits the use of unapproved medical products.

93. During a Public Health Emergency, the Health and Human Services Secretary “may authorize ... during the effective period of a declaration [of a state of emergency] ... a drug, device, or biological product intended for use in an actual or potential emergency.... [The Secretary] may authorize an emergency use of a product that – (A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. § 262] or conditionally approved under section 360ccc of this title ... (referred to in this section as unapproved product)....” 21 U.S.C. § 360bbb-3(a)(1)-(2) (emphasis added).

§360bbb–3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).

(2) Approval status of product


An authorization under paragraph (1) may authorize an emergency use of a product that-

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an “unapproved product”); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an “unapproved use of an approved product”).

94. As required by 21 U.S.C. § 360bbb-3(b)(4), “the Secretary shall promptly publish in the Federal Register each declaration, determination, and advance notice of termination under this subsection.” 85 Fed. Reg. 52, 15198-15203 (March 17, 2020) (emphasis added).

95. On March 17, 2020, the Health and Human Services Secretary published his Declaration in the Federal Register.

 15198 Federal Register / Vol. 85, No. 52 / Tuesday, March 17, 2020 / Notices		
Ohio, Court of Federal Claims No: 20–0225V 71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V 72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V [FR Doc. 2020–05525 Filed 3–16–20; 8:45 am] BILLING CODE 4165–15–P	enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of “Covered Countermeasures” and “qualified pandemic and epidemic products” in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or	requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19. ² Description of This Declaration by Section <i>Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency</i> Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public
DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 ACTION: Notice of declaration. SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to		

96. As required by 21 U.S.C. § 360bbb-3(b)(2)(A), a “Declaration under this subsection shall terminate upon the earlier of- (i) a determination by the Secretary ... that the circumstances [public health emergency] described in paragraph (1) have ceased to exist; or (ii) a change in approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.”

(2) Termination of declaration

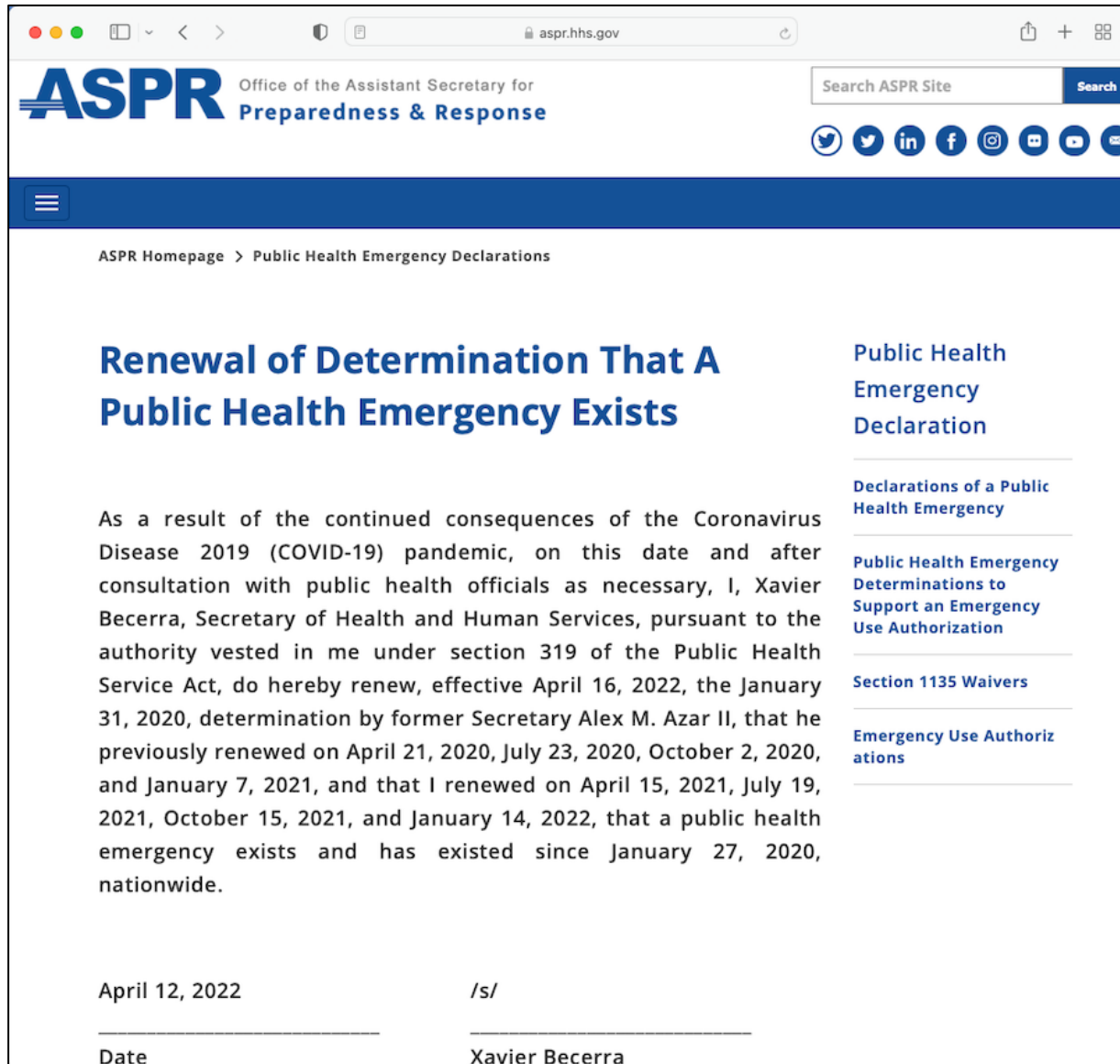
(A) In general

A declaration under this subsection shall terminate upon the earlier of-

- (i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or
- (ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

97. As discussed *supra*, on April 12, 2022, Health and Human Services Secretary Xavier Becerra renewed his determination that a Public Health Emergency existed in the United States.

98. The public health emergency is not scheduled to expire until July 15, 2022.



99. The Secretary of Health and Human Services has published ten amendments to his original Declaration.

100. The Secretary's most recent Declaration was filed on January 7, 2022. Federal Register, Vol. 87, No. 5, pp. 982-88 <https://www.govinfo.gov/content/pkg/FR-2022-01-07/pdf/2022-00151.pdf> (last accessed July 10, 2022).

<p>for states to submit reports on supplemental payments as defined in section 1903(bb)(2) of the Act. States are required to submit "reports, as determined appropriate by the Secretary, on supplemental payment data, as a requirement for a State plan or State plan amendment [SPA] that would provide for a supplemental payment" as required by section 1903(bb)(1) of the Act.</p> <p>CMS is implementing section 202 of the CAA of 2021 by adding new screens to the CMS-64 in the MBES system for states to report all supplemental payments. States will be expected to use the form starting for their first quarter Federal fiscal year 2022 expenditures beginning on January 15, 2022. The statute requires CMS to set up a data collection system for all state supplemental payments. <i>Form Number:</i> CMS-10398 (#73) (OMB control number: 0938-1148); <i>Frequency:</i> Yearly; <i>Affected Public:</i> State, Local, or Tribal Governments; <i>Number of Respondents:</i> 54; <i>Total Annual Responses:</i> 54; <i>Total Annual Hours:</i> 3,240. (For policy questions regarding this collection contact: Richard Kimball at 410-786-2278.)</p> <p>4. <i>Title of Information Collection:</i> Coverage of Routine Patient Cost for Items & Services in Qualifying Clinical Trials; <i>Type of Information Collection Request:</i> New collection; <i>Use:</i> Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act) to add a new mandatory benefit at 1905(a)(30). The new benefit mandates coverage of routine patient services and costs furnished in connection with</p>	<p>requirements of a federally sponsored clinical trial is appropriate for the Medicaid beneficiary. <i>Form Number:</i> CMS-10398 (#74) (OMB control number: 0938-1148); <i>Frequency:</i> Yearly; <i>Affected Public:</i> State, Local, or Tribal Governments; <i>Number of Respondents:</i> 56; <i>Total Annual Responses:</i> 56; <i>Total Annual Hours:</i> 56. (For policy questions regarding this collection contact Kirsten Jensen at 410-786-8146.)</p> <p>5. <i>Title of Information Collection:</i> American Rescue Plan (ARP) 1135 State Plan Amendment; <i>Type of Information Collection Request:</i> New collection; <i>Use:</i> Section 9811 of the ARP established new mandatory benefits at section 1905(a)(4)(E) for COVID-19 vaccine and vaccine administration and section 1905(a)(4)(F) for COVID-19 testing and treatment for both Medicaid and CHIP. The effective date time period for these mandatory benefits is March 11, 2021, ending on the last day of the first calendar quarter that begins one year after the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (the Act). Given that regular state plan rules do not allow for effective dates prior to the first day of the quarter in which the state plan amendment (SPA) was submitted, we are allowing states to use Section 1135 SPA process waiver authority to allow states to meet the required timeframes of these provisions. The SPAs will implement mandatory Medicaid coverage and reimbursement for COVID-19 vaccine and vaccine administration and COVID-19 testing and treatment are considered part of the Agency's emergency response to COVID.</p>	<p>BILLING CODE 4120-01-P</p> <p>DEPARTMENT OF HEALTH AND HUMAN SERVICES</p> <p>Office of the Secretary</p> <p>Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19</p> <p>ACTION: Notice of amendment.</p> <p>SUMMARY: The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to expand the authority for certain Qualified Persons authorized to prescribe, dispense, and administer seasonal influenza vaccines under section VI of this Declaration.</p> <p>DATES: This amendment is effective as of January 7, 2022.</p> <p>FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202-260-0365, paige.ezernack@hhs.gov.</p> <p>SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of,</p>
<p align="center">Federal Register / Vol. 87, No. 5 / Friday, January 7, 2022 / Notices</p>		<p align="right">983</p>

101. As required by 21 U.S.C. § 360bbb-3(b)(2)(A), a "Declaration under this subsection shall terminate upon the earlier of- (i) a determination by the Secretary ... that the circumstances

[public health emergency] described in paragraph (1) have ceased to exist; or (ii) a change in approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.”

As presented *supra*, there has been an ongoing declared Public Health Emergency in the United States since January 31, 2020. *See infra*.

102. Since the declared Public Health Emergency has not expired, the United States Air Force must administer the COVID-19 injections in accordance with federal law and the Code of Federal Regulations.

(2) Termination of declaration

(A) In general

A declaration under this subsection shall terminate upon the earlier of-

- (i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or
- (ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

103. Pursuant to 21 U.S.C. § 360bbb-3(e), there are “required conditions” that must be met as part of an emergency use of an “unapproved product” during a Public Health Emergency. “With respect to the emergency use of an unapproved product, the Secretary ... **shall** ... establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following: ... (ii) Appropriate conditions designed to ensure that **individuals to whom the product is administered are informed**— ... (II) of the significant known and potential benefits and **risks of such use**, and of the extent to which such benefits and **risks are unknown**; and (III) **of the option to** accept or **refuse administration of the product**, of the [health] consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” 21 U.S.C. § 360bbb-3(e)(1)(A) (emphasis added).

(e) Conditions of authorization**(1) Unapproved product****(A) Required conditions**

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed-

- (I) that the Secretary has authorized the emergency use of the product;
- (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
- (III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed-

- (I) that the Secretary has authorized the emergency use of the product;
- (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
- (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

104. Stated slightly different, federal law requires that people be given an option “**to refuse** administration of the [unapproved] product [COVID-19 vaccine]” during a Public Health Emergency that is administered under the Emergency Use Authorization. *See id* (emphasis added).

105. The conditions of authorization for an unapproved product, which includes but is not limited to the COVID-19 injections, require the United States Air Force to notify Lt. Col. Wiese of her right and her option to refuse administration of the unapproved COVID-19 injection.

H. The Code of Federal Regulations require that human beings must be given a choice on “whether to participate” as a subject in research with an unapproved medical product.

106. The Code of Federal Regulations applies to all FDA regulated clinical investigations.

21 C.F.R § 50.1.

107. The Code of Federal Regulations applies to clinical investigations regulated by the FDA and clinical investigations that support applications for research for products regulated by the FDA, which includes “drugs for human use”. *See id.*

7/30/2021
Electronic Code of Federal Regulations (eCFR)

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of July 28, 2021

Title 21 → Chapter I → Subchapter A → Part 50 → Subpart A → §50.1

Title 21: Food and Drugs
PART 50—PROTECTION OF HUMAN SUBJECTS
Subpart A—General Provisions

§50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

108. “Compliance with [the Code of Federal Regulations] is intended to **protect the rights and safety of subjects involved in investigations** filed with the Food and Drug Administration....”

Id (emphasis added).

109. The Code of Federal Regulations requires that people – *i.e.*, human beings, ALL HUMAN BEINGS – must be given a choice on “whether or not to participate” as a subject in research

with an unapproved vaccine. *See* 21 C.F.R. § 50.20. All of the current COVID-19 injections are unapproved by the FDA. *See* ¶¶ B.1 to B.3 *supra*.

110. As all COVID-19 vaccines [sic] are currently unapproved, the Code of Federal Regulations requires that “no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject.... An investigator shall seek such consent only under circumstances that provide the prospective subject ... sufficient opportunity to consider whether OR NOT to participate and that minimize the possibility of COERCION or UNDUE INFLUENCE.” 21 C.F.R. § 50.20 (emphasis added).

7/30/2021
Electronic Code of Federal Regulations (eCFR)

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of July 28, 2021

Title 21 → Chapter I → Subchapter A → Part 50 → Subpart B → §50.20

Title 21: Food and Drugs
PART 50—PROTECTION OF HUMAN SUBJECTS
Subpart B—Informed Consent of Human Subjects

§50.20 General requirements for informed consent.

Except as provided in §§50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

[46 FR 8951, Jan. 27, 1981, as amended at 64 FR 10942, Mar. 8, 1999]

I. The Food and Drug Administration’s guidance requires that test subjects in research be provided with the option to accept or refuse participation in a clinical trial with the experimental COVID-19 injections.

111. The Food and Drug Administration (“FDA”) issues guidance, which is the current thinking of the FDA on the Emergency Use Authorization (“EUA”) topic. *See* Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders, U.S. Department of Health and Human Services, Food and Drug Administration, p. 1 (January 2017) (attached as Exhibit 13).

**Emergency Use Authorization of Medical Products
and Related Authorities¹**

Guidance for Industry and Other Stakeholders

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

112. The scope of the FDA’s Guidance is “intended to inform all stakeholders¹ involved in emergency response activities and FDA staff of FDA’s general recommendations and procedures for

¹ For purposes of this guidance, “stakeholders” include industry and government sponsors and other government stakeholders/entities involved in emergency response activities (including Federal, State, local, tribal, or territorial government stakeholders/entities). The term “government stakeholders” refers to the public health and/or emergency response agencies or their agents/delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundaries (*e.g.*, city, county, tribal, territorial, State, or Federal), or functional range or sphere of authority (*e.g.*, law enforcement, public health, **military health**) to prescribe, administer, deliver, distribute, hold, or dispense a medical product during an emergency situation. (emphasis added).

Issuance of EUAs, implementation of emergency use authorities and reliance on the governmental pre-positioning authority. *Id* at 2.

113. While the FDA Guidance is not mandatory, **it summarizes the law and provides help on how to implement and use the products under an Emergency Use Authorization.** The United States Air Force is aware of, or should be aware of, the FDA Guidelines for Emergency Use Authorization of Medical Products.

II. SCOPE OF GUIDANCE

This document is intended to inform all stakeholders⁵ involved in emergency response activities and FDA staff of FDA's general recommendations and procedures for:

- (1) Issuance of Emergency Use Authorizations (EUAs) under section 564;
- (2) Implementation of the emergency use authorities set forth in section 564A; and
- (3) Reliance on the governmental pre-positioning authority set forth in section 564B."

114. The FDA Guidelines instruct government that the statute requires that FDA ensures that recipients of an EUA product are informed "That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product..." *See id.*

b. Information for Recipients

Although informed consent as generally required under FDA regulations⁴⁵ is not required for administration or use of an EUA product, section 564 does provide EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA. For an unapproved product (section 564(e)(1)(A)(ii)) and for an unapproved use of an approved product (section 564(e)(2)(A)), the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances:

- That FDA has authorized emergency use of the product;
- Of the significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown;
- That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product;⁴⁶ and
- Of any available alternatives to the product and of the risks and benefits of available alternatives.

G. The United States Air Force as well as other branches of the military bend over backwards to accommodate other religions such those that identify as Muslim and/or Jewish but actively persecute the Christians by employing double standard on religious accommodations which is the definition of unlawful discrimination.

115. The United States Air Force has no authority to mandate an unapproved medical product, such as the COVID-19 vaccines [sic].

116. However, even if the United States Air Force had the authority to mandate the unapproved COVID-19 vaccines [sic], then the United States Air Force must nonetheless provide Plaintiff with a religious accommodation and exempt her from the COVID-19 vaccine [sic] mandate.

117. The Air Force bends over backwards to provide “religious accommodations” to those of Muslim and Jewish faiths for their sincerely held religious beliefs, but the Air Force actively persecutes the Christians by employing a hypocritical double standard when it pertains to providing a religious accommodation for the Christians’ sincerely held religious beliefs.

118. The Air Force is **required** to provide accommodations to the Christians; not just to those that prescribe to the Muslim and Jewish faith.

119. “BY ORDER OF THE SECRETARY OF THE AIR FORCE,” religious freedom must be recognized by the Air Force chain of command “RELIGIOUS FREEDOM IN THE DEPARTMENT OF THE AIR FORCE”. Department of the Air Force Instruction dated 23 June 2021, https://static.e-publishing.af.mil/production/1/af_hc/publication/dafi52-201/dafi52-201.pdf (last visited July 10, 2022).

**BY ORDER OF THE
SECRETARY OF THE AIR FORCE**



**DEPARTMENT OF THE AIR FORCE
INSTRUCTION**

52-201

23 JUNE 2021

Chaplain

**RELIGIOUS FREEDOM IN THE
DEPARTMENT OF THE AIR FORCE**

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

ACCESSIBILITY: Publications and forms are available on the e-Publishing website at www.e-Publishing.af.mil for downloading or ordering.

RELEASABILITY: There are no releasability restrictions on this publication.

OPR: DAF/HCX

Certified by: AF/HCX
(Ch, Lt Col Chris Conklin)

Pages: 37

120. The Secretary of the Air Force requires the United States Air Force to “place a high value on the rights of Airmen and Guardians” and “to observe the tenants of their respective religions....” *Id* at p. 2, Section 1.1.

121. “Commanders **must** create an environment in which Airmen and Guardians are **free to practice their religious** or secular **worldview**, while respecting the beliefs of others, unless such practices have an adverse impact on mission accomplishment, military readiness, unit cohesion, good order and discipline, health or safety.

122. The covid-19 injection has no adverse impact on mission accomplishment.

123. Lt. Col. Wiese has been accomplishing her mission and excelling in her job since 2019 and throughout the entire declared Public Health Emergency.

124. Military readiness is not affected because nothing can prevent the transmission of COVID-19. Dr. Craig Wax testified under oath that “**no COVID-19 vaccines [sic] are proven to prevent SARS-COV-2 (COVID-19) virus or person-to-person transmission or spread.**” *Avery Garfield v. Middle Tennessee State University and Dr. Jenny Sauls*, Plaintiff’s Rule 26 Disclosures, p. 217 of 215, ¶ 21 (emphasis added).

125. Since the vaccine cannot prevent transmission of COVID-19, the vaccination status is a moot point and cannot adversely affect unit cohesion or mission readiness.

126. An Airman’s vaccination status has no adverse impact on good order, discipline, health or safety.

127. There is no reason not to accommodate Lt. Col. Wiese’s sincerely held religious beliefs.

128. The Secretary of the Air Force has Instructed the United States Air Force that “A member’s expression of sincerely held beliefs may not be used as the basis for any adverse personnel action, discrimination, or denial of promotion; and may not be used as a basis for making schooling, training, or assignment decisions.” RELIGIOUS FREEDOM IN THE DEPARTMENT OF THE AIR FORCE”. Department of the Air Force Instruction dated 23 June 2021, https://static.e-publishing.af.mil/production/1/af_hc/publication/dafi52-201/dafi52-201.pdf (last visited July 10, 2022), Section 1.3.

129. Section 2.2 states that an Airman has a right to request a religious accommodation is based upon the U.S. Constitution and federal statutes.

130. Specifically the policy states and provides as follows:

2.2. Airmen and Guardians may request religious accommodations from a policy, practice, or duty. As the right to request religious accommodation is based on the U.S. Constitution and federal statutes, it is critically important to fully consider and appropriately value an Airman's or Guardian's request. Airmen and Guardians may request religious accommodation when the request is grounded in a sincerely held belief, but a DoD or DAF mandated policy, practice, or duty substantially burdens the exercise of it.

2.2.1. The first question to answer is whether the request is based on the expression of sincerely held beliefs (e.g., conscience, moral principles, or religious beliefs). If it is based on a sincerely held belief, the relevant expression can include any religious practice, whether compelled by, or central to, an organized system of religious belief.

2.2.2. The second question is whether the policy, practice, or duty from which the member is requesting accommodation substantially burdens the expression of that belief.

2.2.3. A governmental act is a substantial burden to a Service member's exercise of religion if it:

2.2.3.1. Requires participation in an activity prohibited by a sincerely held religious belief;

2.2.3.2. Prevents participation in conduct motivated by a sincerely held religious belief; or

2.2.3.3. Places substantial pressure on a Service member to engage in conduct contrary to a sincerely held religious belief.

2.3. The Department of the Air Force will approve a member's request for religious accommodation unless the request would have a real (not theoretical) adverse impact on military readiness, unit cohesion, good order, discipline, health or safety.

131. The Air Force bends over backwards to accommodate the sincerely held religious beliefs of Muslims and Jewish Airmen.

132. Captain Maysaa Ouza was a Muslim lawyer who wanted to join the Air Force, but she wears a hijab that covers her hair, which is not allowed in the Air Force.

133. Ouza wanted pre-approval from the Air Force to wear her hijab, stating that she didn't know what she would do without it: "I would essentially be forced to choose between representing my faith or serving my country," she told CBS News. "And I felt conflicted because I identify as a Muslim American and I wanted nothing more than to serve my country." Air Force captains bond over religion, even though they practice different ones, <https://www.cbsnews.com/news/maysaa-ouza-joe-hochheiser-hijab-yarmulke-air-force-religious-accommodation/> (last visited July 8, 2022).

134. Ultimately, “She not only received religious accommodation for training, she sought to get the Air Force's to change the policy. And they did – allowing others to now get pre-approval for religious accommodations before they joined training.” *Id.*



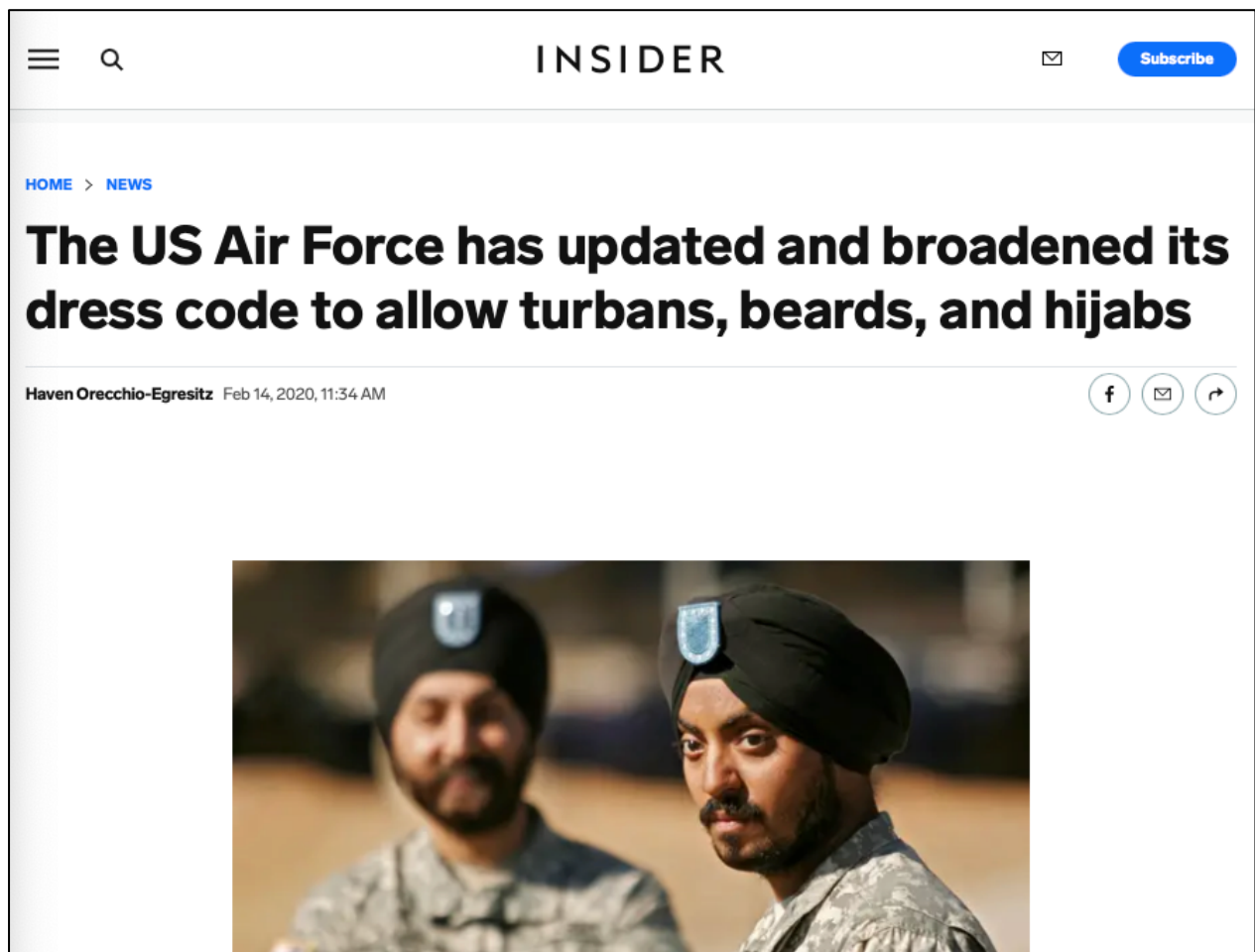
135. Female Muslims receive a religious accommodation for their sincerely held religious beliefs and are permitted to wear a hijab, which otherwise would violate Air Force dress code.

136. The Jewish males receive a religious accommodation for their sincerely held religious beliefs and are permitted to wear a yarmulke, which would otherwise violate Air Force dress code.

137. Muslim males receive a religious accommodation for their sincerely held religious beliefs and are permitted to wear a turbans, which would otherwise violate Air Force dress code.

138. The US Air Force has updated and broadened its dress code to allow turbans, beards and hijabs, <https://www.insider.com/air-force-has-updated-its-dress-code-to-allow-turbans-beards-and-hijabs-2020-2> (last visited July 8, 2022).

139. Muslim males receive a religious accommodation for their sincerely held religious beliefs and are permitted to grow a beard, which would otherwise violate Air Force dress code. *Id.*



140. Jewish and Muslim Airmen also have diet restrictions pursuant to sincerely held religious beliefs.

141. In order to accommodate the Muslim and Jewish Airmen, the United States Air Force provides Religious MREs, or Meal Ready-to-Eat. The Air Force makes religious accommodations for the Airmen who maintain a strict religious diet and, as a result, provides Religious MREs.

142. Online it was reported that a Muslim Airman was excused from physical training during the entire month of Ramadan. The Air Force apparently provided a religious accommodation to this Muslim Airman because he fasts during the day, meaning he doesn't eat or drink during the entire day (literally sun up to sun down) during the entire month. It's reported that the Air Force provided him with a religious accommodation and excused him from all physical training during a month-long holiday. Muslim Airman in my squadron doesn't have to attend. https://www.reddit.com/r/AirForce/comments/3b5dqy/muslim_airman_in_my_squadron_doesnt_have_to/ (last visited July 10, 2022).

143. Lt. Col. Wiese has a sincerely held religious belief as a Christian and she is vehemently opposed to murdering unborn babies by way of an abortion, even if to use baby cells in a vaccine.

144. The Holy Bible teaches Christians that all lives matter.

145. Unborn lives matter.

146. The Bible teaches as follows:

- a. **Exodus 20:13**: "You shall not murder."
- b. **Leviticus 24:17**: "Whoever takes a human life shall surely be put to death."
- c. **Matthew 18:14**: "So it is not the will of my Father who is in heaven that one of these little ones should perish."

- d. **Exodus 23:7**: “Keep far from a false charge, and do not kill the innocent and righteous, for I will not acquit the wicked.”
- e. **Genesis 9:5-6**: “And for your lifeblood I will require a reckoning: from every beast I will require it and from man. From his fellow man I will require a reckoning for the life of man. “Whoever sheds the blood of man, by man shall his blood be shed, for God made man in his own image.”
- f. **Proverbs 6:16-19**: “There are six things that the Lord hates, seven that are an abomination to him: haughty eyes, a lying tongue, and hands that shed innocent blood, a heart that devises wicked plans, feet that make haste to run to evil, a false witness who breathes out lies, and one who sows discord among brothers.”
- g. **Psalms 139:16**: “Your eyes saw my unformed body; all the days ordained for me were written in your book before one of them came to be.”
- h. **Deuteronomy 30:19**: “I call heaven and earth to witness against you today, that I have set before you life and death, blessing and curse. Therefore choose life, that you and your offspring may live....”
- i. **Jeremiah 20:17**: “Because he did not kill me before birth, so that my mother would have been my grave, and her womb ever pregnant.”
- j. **Psalms 127:3-5**: “Children are a heritage from the LORD, offspring a reward from him. Like arrows in the hands of a warrior are children born in one’s youth. Blessed is the man whose quiver is full of them. They will not be put to shame when they contend with their opponents in court.”

147. In Christianity, as demonstrated above, there are many verses in all versions of the Christian Bibles that present the Christian principles that all lives matter to the Lord Jesus Christ.

148. Christianity condemns murdering the innocent.

149. Christianity condemns murdering children.

150. Christianity condemns murdering unborn children.

151. Christianity condemns murdering unborn children for the purpose of using their cells in the COVID-19 vaccines [sic].

152. Christianity teaches that there is to be severe punishment when an unborn child dies as a result of another’s actions, because the unborn child is another human being who is separate and distinct from his/her mother.

153. The COVID-19 injections are made with cells from babies that were murdered by way of an abortion and this is an abomination to Christians, specifically to Lt. Col. Wiese.

154. Lt. Col. Wiese has a sincerely held religious belief that the United States Air Force must accommodate.

155. In violation of federal law, which requires informed consent and an option to refuse to participate in an unapproved vaccination program, the Defendants mandated that Plaintiff take the vaccine and that there would be no exceptions.

156. In violation of federal law, which requires informed consent and an option to refuse to participate in an unapproved vaccination program, the Defendants are mandating that Plaintiff take part in unapproved experimental medicine against her will.

157. In violation of federal law, which requires informed consent and an option to refuse to participate in an unapproved vaccination program, the Defendants mandated that Plaintiff take part in unapproved experimental medicine against her will to avoid being separated and/or forced to retire.

158. In violation of federal law, which requires informed consent and an option to refuse to participate in an unapproved vaccination program, the Defendants are demanding compliance with the COVID-19 guidelines and unlawfully threatened Plaintiff consequences if she does not start the COVID-19 vaccination regimen.

159. On June 29, 2022, Plaintiff's final appeal for her Religious Accommodation Request was denied. (Decision on Religious Accommodation Request attached hereto as Exhibit 14).

160. On July 5, 2022, Plaintiff received notification and an Order to receive the mandatory COVID-19 vaccine within five (5) days or to "submit a request to separate or retire no later than the first day of the fifth month following the this final appeal denial." (Memorandum for Lieutenant Colonel Carla A. Wiese, 60 MDG is attached hereto as Exhibit 15).



DEPARTMENT OF THE AIR FORCE
60TH MEDICAL GROUP (AMC)



5 July 2022

MEMORANDUM FOR LIEUTENANT COLONEL CARLA A. WIESE, 60 MDG

FROM: 60 MDG/CC

SUBJECT: Religious Accommodation Request Final Appeal Decision Notification and Order to
Receive Mandatory COVID-19 Vaccine

...

1. On 29 June 2022, DAF/SG denied your religious accommodation request final appeal to be exempted from taking the COVID-19 vaccine (attached). You were served with DAF/SG's decision on 5 July 2022.
2. As a result, and in accordance with the above references, I am ordering you to, within **five (5) calendar days** from the date of this order, 1) begin the COVID-19 vaccination regimen; **or** 2) submit a request to separate or retire no later than the first day of the fifth month following this final appeal denial.
3. Failure to comply with this lawful order may result in administrative and/or punitive action for failing to obey an order under Article 92, Uniform Code of Military Justice.

GWENDOLYN A. FOSTER, Colonel, USAF, NC
Commander

Attachment:
DAF/SG Religious Accommodation Request Final Appeal Decision Memo, dated 29 June 2022

IV. COUNT I

**Violation of Plaintiff's Rights Under the Religious Freedom Restoration Act
Duty and Medical Disqualification
42 U.S.C. § 2000bb *et seq.***

161. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully plead herein.

162. The Defendants do not have the lawful authority to mandate Plaintiff to receive an unapproved medical product that is being administered pursuant to the Emergency Use Authorization.

163. Even if the Defendants had the lawful authority to mandate the COVID-19 vaccines [sic], then the Defendants must accept and enforce Plaintiff's sincerely held religious belief and provide Plaintiff with an accommodation/exemption for the COVID-19 vaccine [sic] mandate.

164. The Religious Freedom Restoration Act of 1993, 42 U.S.C. § 2000bb *et seq.* (RFRA), states that the "[g]overnment shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1.

165. The act broadly defines the "exercise of religion" to include "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." 42 U.S.C. § 2000bb-2(4) (citing 42 U.S.C. § 2000cc-5(7)(A)).

166. In *Burwell v. Hobby Lobby Stores*, the Supreme Court stated that the exercise of religion involves "not only belief and profession but the performance of (or abstention from) physical acts that are engaged in for religious reasons." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 710 (2014) (citing *Smith*, 494 U.S. at 877).

167. The Supreme Court has articulated repeatedly that courts may not question whether sincerely held religious beliefs are reasonable. *Hobby Lobby*, 573 U.S. at 724.

168. RFRA imposes strict scrutiny on all actions of the federal government that "substantially burden a person's exercise of religion." 42 U.S.C. § 2000bb-1(b).

169. Unless the government satisfies the compelling interest test by "demonstrat[ing] that [the] application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," 42 U.S.C. § 2000bb-1(b), the governmental act violates RFRA.

170. Plaintiff has sincerely held religious beliefs that she cannot receive the mandated COVID-19 vaccine.

171. Defendants' Vaccine Mandates substantially burden Plaintiff's sincerely held religious beliefs by requiring her to take an action (receiving a COVID-19 vaccine) that would violate those sincerely held religious beliefs or suffer adverse employment action, financial harm, and potential physical harm.

172. The adverse actions to which Plaintiff is subject to may include: court-martial (criminal) prosecution, involuntary separation, relief for cause from leadership positions, removal from promotion lists, inability to attend certain military training and education schools, loss of pay, placement in a non-deployable status, recoupment of money spent training the service member, and loss of leave and travel privileges for both official and unofficial purposes.

173. The COVID-19 vaccines [sic] do not ensure the health of the United States Air Force fleet.

174. The COVID-19 vaccines [sic] do not ensure continued mission accomplishment.

175. The COVID-19 vaccines [sic] do not adversely affect Plaintiff's ability to discharge her duties and to conduct formal and informal research.

176. The COVID-19 vaccines [sic] do not adversely affect Plaintiff's deployment capabilities.

177. The COVID-19 vaccines [sic] do not adversely affect Plaintiff's prevent the transmission of any variant of COVID-19.

178. The COVID-19 vaccines [sic] do not inoculate Plaintiff from COVID-19.

179. The COVID-19 vaccines [sic] do not prevent the spread of COVID-19.

180. Defendants' mandates fail strict scrutiny.

181. Defendants' mandates violate Plaintiff's constitutional right to practice her religion.

182. Defendants' mandates violate Plaintiff's federal statutory right to practice her religion pursuant to the Religious Freedom Restoration Act.

183. Defendants do not have a compelling government interest in requiring Plaintiff to violate her sincerely held religious beliefs by taking a COVID-19 vaccine [sic].

184. As a direct and proximate cause of the Defendants' unlawful mandates, Plaintiff has suffered, and continues to suffer, economic injury, discrimination and irreparable harm.

185. As a result, Plaintiff is entitled to an award of money damages and equitable relief.

186. Plaintiff is also entitled to a declaration that Defendants violated her constitutional rights and her rights under the Religious Freedom Restoration Act.

187. Plaintiff is entitled to a Temporary Restraining Order and a Preliminary Injunction against the Defendants to stop the Defendants from violating her constitutional and federal statutory rights and to stop discriminating against her based upon her vaccination status.

188. Plaintiff is entitled to damages in an amount to be determined by the evidence.

189. Plaintiff is entitled to an award of attorneys' fees, reasonable court costs.

V. COUNT II

Violation of Plaintiff's Rights Under the Religious Freedom Restoration Act Duty and Medical Disqualification U.S. Const., Amend. I

190. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully plead herein.

191. The First Amendment's Free Exercise Clause prohibits the government from enacting non-neutral and non-generally applicable laws or policies unless they are narrowly tailored to a compelling government interest.

192. The original public meaning of the Free Exercise Clause is that the government may not burden a sincerely held religious belief unless the government can demonstrate a compelling interest and that the law or policy burdening religious exercise is the least restrictive means to achieve that compelling interest.

193. Plaintiff has a sincerely held religious belief that prohibits her from receiving the COVID-19 vaccine(s) [sic].

194. The 5 July 2022 Order requiring Plaintiff to start the COVID-19 vaccine [sic] regimen or to submit a request to separate or retire violates Plaintiff's constitutional right to exercise and/or practice her religion.

195. The Defendants' threat that failure to comply with the United States Air Force's 5 July 2022 Order, or face administrative and/or punitive action, is unconstitutional.

196. The Defendants' threat that failure to comply with the United States Air Force's 5 July 2022 Order, or face administrative and/or punitive action, violates Plaintiff's First Amendment rights.

197. Article 92 provides for punitive actions against service members for refusal to comply with a **lawful** order.

198. The Defendants' threat that Plaintiff must comply with this Order is unlawful.

199. The COVID-19 vaccine [sic] mandates are not a lawful Order.

200. The Defendants' threat that failure to comply with the United States Air Force's 5 July 2022 Order, or face administrative and/or punitive action, is illegal and unlawful.

201. The Defendants' actions fail to meet strict scrutiny.

202. The Defendants' actions to force Plaintiff to start the vaccination [sic] regimen or to face punitive action is not the least restrictive means of accomplishing the government's purported interest because the United States Air Force operated for over a year during the COVID-19 pandemic with a ready and healthy force that had not been fully vaccinated.

203. Granting Plaintiff's religious exemption will have no adverse consequence on United States Air Force's readiness, prevention of the spread of COVID-19, unit cohesion and/or unit readiness.

204. Whether or not Plaintiff receives the COVID-19 vaccine [sic] will have no impact on the United States Air Force's ability to stop transmission of COVID-19.

205. Transmission of COVID-19 cannot be accomplished with the COVID-19 vaccine.

206. Defendants have lesser restrictive means of mitigating the spread of COVID-19, including remote work, wearing a mask, social distancing and/or regular testing.

207. Defendants will still need to implement the above-referenced mitigation protocols because preventing transmission of COVID-19 cannot be achieved even if the entire United States Air Force were fully vaccinated [sic].

208. Accordingly, the Defendants actions violate Plaintiff's constitutional right to the free exercise of religion under the First Amendment.

209. Since Plaintiff continues to incur damages and has suffered, and continues to suffer, irreparable harm, Plaintiff is entitled to equitable relief.

210. Plaintiff is entitled to a declaration that her First Amendment rights were violated.

211. Plaintiff is entitled to have this Court enter a Temporary Restraining Order to halt the Defendants' unlawful mandate of an unapproved medical product.

VI. COUNT III

Violation of Plaintiff's Rights Under the Administrative Procedure Act Agency Action Not in Accordance with Law 5 U.S.C. §§ 701-06

212. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully plead herein.

213. Pursuant to 5 U.S.C. § 551, the Defendants are "agencies" and the COVID-19 vaccine [sic] mandates are "rules" under the Administrative Procedure Act. *See* 5 U.S.C. §§ 551(1) and (4).

214. The Defendants' mandates are "[a]gency action for which there is no other adequate remedy in a court...." 5 U.S.C. § 704.

215. The Administrative Procedures Act prohibits agency actions that are "not in accordance with law." 5 U.S.C. § 706(2)(A).

216. The Vaccine Mandates, as applied to Plaintiff, is not in accordance with law.

217. None of the COVID-19 vaccines [sic] have been approved by the FDA.

218. The mandate is illegal and unlawful.

219. However, even if all of the COVID-19 vaccines [sic] had been fully approved by the FDA, then the Defendants must nonetheless accept and recognize Plaintiff's request for a religious accommodation to the COVID-19 vaccines [sic].

220. RFRA states that the "[g]overnment shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1.

221. The agency failed to satisfy the compelling interest test by "demonstrat[ing] that [the] application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," 42 U.S.C. § 2000bb-1(b).

222. The Defendants' actions violate the Religious Freedom Restoration Act and the Administrative Procedures Act.

223. Defendants' Vaccine Mandates substantially burden Plaintiff's sincerely held religious beliefs by requiring her to take an action (receiving a COVID-19 vaccine) that would violate those religious beliefs or suffer adverse employment action and financial harm.

224. Defendants do not have a compelling governmental interest in requiring Plaintiff to violate her sincerely held religious beliefs by unlawfully mandating that Plaintiff take the COVID-19 vaccines [sic].

225. Defendants' mandate is also not the least restrictive means of accomplishing the government's purported interest because Department of Defense and the United States Air Force operated for over a year during the COVID-19 pandemic with a ready and healthy force that had not been fully vaccinated.

226. Defendants possess multiple lesser restrictive methods of mitigating the spread of COVID-19, including masking, remote teleworking, physical distancing, and regular testing.

227. For the reasons discussed above, the Vaccine Mandates are not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A) as they violate Plaintiff's rights under the Religious Freedom Restoration Act.

228. The Defendants' actions are contrary to and violate Plaintiff's express constitutional and federal rights pursuant to U.S. Const., Amend. I, 5 U.S.C. §§ 701-06, and 5 U.S.C. § 551 *et seq.*

229. The Defendants actions exceeds the Defendants' statutory authority. *See* 5 U.S.C. § 701 *et seq.* and 5 U.S.C. § 551 *et seq.*

230. The Defendants actions are arbitrary (unsupported by law), capricious and/or constitute an abuse of discretion. *See id.*

231. Plaintiff has no adequate or available administrative remedy.

232. In the alternative, any effort to obtain an administrative remedy would be futile as Defendants continue to violate federal law and Plaintiff's constitutional rights.

233. Plaintiff has no adequate remedy at law.

234. Absent injunctive and declaratory relief against the Vaccine Mandates, Plaintiff will have been, and will continue to be, harmed by the Defendants' unlawful conduct.

235. The adverse actions to which Plaintiff is subject may include: (1) court-martial (criminal) prosecution; (2) involuntary separation; (3) relief for cause from leadership positions; (4) removal from promotion lists; (5) inability to attend certain military training and education schools; (6) loss of pay; (7) placement in a non-deployable status; (8) subject to recoupment of money spent training the service member; and (9) loss of leave and travel privileges for both official and unofficial purposes.

PRAYER FOR RELIEF

WHEREFORE, premises considered, Plaintiff prays as follows:

1. That good and adequate service be had on Defendants, **Joseph R. Biden, Jr.**, in his official capacity as the President of the United States of America, **Lloyd J. Austin**, in his official capacity as United States Secretary of Defense, **Frank Kendall**, in his official capacity as Secretary of the Air Force and **General Michael A. Minihan**, in his official capacity as Commander of the United States Air Force Air Mobility Command;
2. That this Honorable Court GRANT Plaintiff's Motion for Temporary Restraining Order to halt the Defendants' illegal and unlawful conduct;
3. That this Honorable Court set the hearing for Plaintiff's Preliminary Injunction;
4. That this Honorable Court issue declaratory judgment that Defendants' COVID-19 vaccination [sic] policies violate Plaintiff's constitutional rights under the First Amendment to the United States Constitution;
5. That this Honorable Court issue declaratory judgment that Defendants' COVID-19 vaccination [sic] policies violate Plaintiff's rights under the Religious Freedom Restoration Act;
6. That this Honorable Court issue declaratory judgment that Defendants' COVID-19 vaccination [sic] policies violate Plaintiff's rights under the Administrative Procedure Act;

7. That this Honorable Court issue a permanent injunction prohibiting the Defendants their agents, officials, servants, employees, and any other persons acting on their behalf from enforcing the vaccination [sic] policies challenged in this Complaint;

8. That this Honorable Court enter an order declaring unlawful and setting aside all of Defendants' COVID-19 vaccination [sic] policies;

9. An award of actual damages, under *Tanzin v. Tanvir*, 141 S. Ct. 486 (2020), in the amount of pay Plaintiffs will lose as a result of Defendants' discriminatory vaccine policies under the Religious Freedom Restoration Act;

10. An award of nominal damages against Defendants in their individual capacities, under *Tanzin v. Tanvir*, 141 S. Ct. 486 (2020), for the violation of Plaintiffs' rights under the Religious Freedom Restoration Act;

11. To empanel a jury of twelve (12) persons to try all issues of fact;

12. Plaintiffs' reasonable attorneys' fees, costs, and other costs and disbursements in this action pursuant to 42 U.S.C. § 1988; and

13. All other further relief to which Plaintiff may be entitled.

Respectfully submitted this 10th day of July, 2022.

THE NEWMAN LAW FIRM

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